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Cynthia L. Foulke NATIONAL STARCH AND CHEMICAL COMPANY 10 Finderne Avenue Bridgewater, NJ 08807-0500			EXAMINER	
			GHALI, ISIS A D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/955,644	Applicant(s) SILVERBERG ET AL.
	Examiner Isis A. Ghali	Art Unit 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 January 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3-7,9-19 and 21-23 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3-7 and 9-19, 21-23 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-640)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 01/05/2009.

Claims 2, 8 and 20 have been canceled. Claim 23 has been added.

Claims 1, 3-7, 9-19, 21-23 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/05/2009 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,491,070 ('070).

The present claim 1 is drawn to polymer comprising 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers and 2-50% non-cyclic nitrogen containing monomer; and therapeutic agent.

US '070 disclosed excellent pressure sensitive adhesive with good tack obtained by the combination of monomers to form polymers comprising of 80-96% of 2-ethylhexyl acrylate and 2.0-19% of octyl acrylamide to create a polymer combination that is synergistic in nature (col.1, lines 52-60, examples and samples B-J). The Tg as claimed by claim 4 is inherent by the teaching of the reference because the reference disclosed polymer comprising the same monomers in amounts falling within the claimed ranges. The polymer disclosed by the reference does not contain functional groups or post polymerization chemical crosslinking as required by the present claim 1. The pressure sensitive adhesive further comprises ammonium persulfate that is known as antimicrobial agent as evident by US 5,827,505, which reads on therapeutic agent. Therefore, the limitations of claims 1, 3-7 and 9 are met by US '070.

Response to Arguments

4. Applicant's arguments filed 01/05/2009 have been fully considered but they are not persuasive. Applicants argue that US '070 must contain only 2-ethylhexyl acrylate, N-octyl acrylamide and methylacrylamide, and requires all three. Applicants' polymer is

prepared from alkyl acrylate monomer and/or alkyl methacrylate monomers having up to about 18 carbon atoms in the alkyl group, N-substituted acrylamide monomers, N-substituted methacrylamide monomers, vinylacetamides, and nitriles, and must contain 50 to about 98% of the alkyl acrylate and/or alkyl methacrylate monomers and from about 2 to about 50% of the recited nitrogen-containing monomers. No other monomers are included.

In response to these arguments, applicants' attention is drawn to the present claim 1 that recites: "wherein said polymerizable non-cyclic nitrogen-containing monomers are selected from the group consisting of N-substituted acrylamide monomers, N-substituted methacrylamide monomers, vinylacetamides, nitriles, and mixtures thereof". Methylacrylamide monomer is further claimed by claim 6. Therefore, N-substituted methacrylamide or its mixture with N-octyl acrylamide are within the scope of the present claims as permitted by reciting "mixture thereof". Further, the expression "comprising" in the preamble of claim 1 does not exclude other elements or materials even in major amounts including other polymerizable monomers in the adhesive composition., see *Cues Inc. vs. Polymer Industries*, USPQ 2d 1847 (DC ND GA 1988); *Moleculon Research Corporation v CBS, Inc.* 229 USPQ 805, *In re Baxter* 210 USPQ 795, 803. The ranges as claimed permit the presence of other monomers because if 60% of the acrylate monomer is used and 30% of non-cyclic nitrogen-containing monomer, then, this will form 90% polymer, and the remaining 10% can be another monomer. Therefore, methylacrylamide monomer disclosed by the reference is within the scope of the present claims as an essential element that is a nitrogen-containing

monomer. Regarding the limitation of "no post-polymerization crosslinking", applicants' attention is directed to the present disclosure in page 5, lines 10-13, wherein applicants disclosed that: "No post-polymerization chemical cross-linking means that while monomers having multiple polymerization sites may be used to prepare the adhesive of the invention, following polymerization no reactive sites are present in the polymer." In view of applicants' definition to "no post polymerization crosslinking", and since the reference disclosed the same percentage of the monomers as instantly claimed, it is implied that all the reactive sites are reacted and no free reactive sites are present after polymerization, i.e. no crosslinking are present following polymerization. The reference does not disclose presence of functional groups after polymerization.

Applicants further argue US '070 fails to disclose an adhesive comprising a therapeutic agent. While US '505 teaches that ammonium persulfate is a known microbial agent, US '070 used ammonium persulfate as an oxidizing agent that is consumed in the polymerization.

In response to this argument, it is noticed that the claims included in this rejection are not directed to any specific therapeutic agent. US '070 disclosed that the pressure sensitive adhesive comprises ammonium persulfate that is known as therapeutic agent as evident by US '505. The present invention is directed to composition, and all the elements of the composition are disclosed by US '070, and the future intended use of specific ingredients, such as ammonium persulfate does not impart patentability to the claims.

5. Claims 1, 3-6, 9-14 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 531 938 ('938).

The present claims 1, 12 and 22 are drawn to polymer comprising 50-98% alkyl acrylate monomers and/or alkyl methacrylate monomers and 2-50% non-cyclic nitrogen containing monomer; and therapeutic agent. Claims 12 and 22 further directed to transdermal devices comprises said polymer.

EP '938 disclosed medical preparation for percutaneous absorption of drugs (abstract). The preparation is applied on a substrate, i.e. backing (page 3, lines 14-20). The preparation comprises pressure sensitive acrylic based layer obtained by polymerizing 60-98% by weight of alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and from 2-40% by weight of monomer copolymerizable with the alkyl (meth)acrylate (page 4, lines 13-19; page 26, claim 5). The alkyl (meth)acrylate is ethylhexyl acrylate (page 4, lines 21-22; example 1). The monomer copolymerizable with the alkyl (meth)acrylate includes (meth)acrylmide, meeting claim 6, and (meth)acrylonitrile, meeting claim 3 (page 4, lines 29, 36). The drugs included in the adhesive layer include analgesics, hypnotics and sedatives (page 6, lines 15-21). The Tg as claimed by claim 4 is inherent by the teaching of the reference because the reference disclosed polymer comprising the same monomers in amounts falling within the claimed ranges. The polymer disclosed by the reference does not contain functional groups or post polymerization chemical crosslinking as required by the present claims 1, 12, and 22.

Response to Arguments

6. Applicant's arguments filed 01/05/2009 have been fully considered but they are not persuasive. Applicants argue that EP '938 does not teach the present adhesive polymer because applicants' polymer lacks functional groups containing reactive moieties and contains no post polymerization chemical crosslinker. EP'938 fails to disclose the adhesive comprises a therapeutic agent as required in the practice of applicants' invention.

In response to this argument, it is argued that EP '938 clearly disclosed polymer obtained by polymerizing 60-98% by weight of alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and from 2-40% by weight of monomer copolymerizable with the alkyl (meth)acrylate. The alkyl (meth)acrylate is ethylhexyl acrylate. The monomer copolymerizable with the alkyl (meth)acrylate includes (meth)acrylmid and (meth)acrylonitrile. The reference does not disclose any crosslinking after polymerization or any functional groups. Further, the reference disclosed therapeutic agents included in the adhesive layer include analgesics, hypnotics and sedatives. Therefore the rejected claims are anticipated by EP '938. The disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Regarding the limitation of "no post-polymerization crosslinking", applicants' attention is directed to the present disclosure in page 5, lines 10-13, wherein applicants disclosed that: "No post-polymerization chemical cross-linking means that while

monomers having multiple polymerization sites may be used to prepare the adhesive of the invention, following polymerization no reactive sites are present in the polymer." In view of applicants' definition to "no post polymerization crosslinker", and since the reference disclosed the same percentage of the monomers as instantly claimed, it is implied that all the reactive sites are reacted and no free reactive sites are present after polymerization, i.e. no crosslinker are present following polymerization.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 3-7, 9-14, and 22 are rejected under 35 U.S.C. 103(a) as being obvious over EP 0 531 938 ('938) in view of US 3,491,070 ('070).

EP '938 teaches medical preparation for percutaneous absorption of drugs (abstract). The preparation is applied on a substrate, i.e. backing (page 3, lines 14-20). The preparation comprises pressure sensitive acrylic based layer obtained by polymerizing 60-98% by weight of alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and from 2-40% by weight of monomer copolymerizable with the alkyl (meth)acrylate (page 4, lines 13-19; page 26, claim 5). The alkyl (meth)acrylate is ethylhexyl acrylate (page 4, lines 21-22; example 1). The monomer copolymerizable with the alkyl (meth)acrylate includes (meth)acrylmide, meeting claim 6, and (meth)acrylonitrile, meeting claim 3 (page 4, lines 29, 36). The drugs included in the adhesive layer include analgesics, hypnotics and sedatives (page 6, lines 15-21). The Tg as claimed by claim 4 is expected to be the same as instantly claimed because the reference disclosed polymer comprising the same monomers in amounts falling within the claimed ranges. The polymer disclosed by the reference does not contain functional groups or post polymerization chemical crosslinking as required by the present claims 1, 12, and 22.

Although EP '938 teaches polymer made by copolymerizing alkyl acrylate monomers and methacrylamide, however, the reference does not exemplify the combination, and does not explicitly teach octyl acrylamide claimed in claims 7.

US '070 disclosed excellent pressure sensitive adhesive with good tack obtained by the combination of monomers to form polymers comprising of 80-96% of 2-ethylhexyl

acrylate and 2.0-19% of octyl acrylamide to create a polymer combination that is synergistic in nature (col.1, lines 52-60, examples and samples B-J).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pressure sensitive acrylic based adhesive obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and methacrylamide monomer as disclosed by EP '938, and replace the acrylamide monomer with octyl acrylamide disclosed by US '070. One would have been motivated to do so because US '070 teaches that the combination of alkyl (meth)acrylate and octyl acrylamide has a good tack and creates a polymer combination that is synergistic in nature. One would have reasonably expected formulating polymer adhesive composition obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and octyl acrylamide to provide polymer that has good tack and synergistic adhesive nature.

Response to Arguments

10. Applicant's arguments filed 01/05/2008 have been fully considered but they are not persuasive. Applicants argue that the claimed invention would not have been obvious from the combined disclosures of EP '938 and US '070 and the use of octyl acrylamide in the practice of the EP '938 invention would not have resulted in an adhesive comprising a acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinker.

In response to this argument, it is argued that EP '938 clearly disclosed polymer obtained by polymerizing 60-98% by weight of alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and from 2-40% by weight of monomer copolymerizable with the alkyl (meth)acrylate. The alkyl (meth)acrylate is ethylhexyl acrylate. The monomer copolymerizable with the alkyl (meth)acrylate includes (meth)acrylmid and (meth)acrylonitrile. Further the reference disclosed the same percentage of the monomers as instantly claimed, and this implies that all the reactive sites are reacted and no free reactive sites are present after polymerization, i.e. no crosslinker are present following polymerization, in view of applicants' definition of "no post polymerization cross linker", as set forth in section 5 of this office action. Replacing nitrogen containing monomer by another known to be suitable to perform the same function is within the skill of artisan versed in the art, specially EP '938 teaches butyl-acrylamide (page 4, line 29). The burden is on applicants to show that substituting acrylamide monomer disclosed by EP '938 with octyl acrylamide disclosed by US '070 would not have resulted in an adhesive comprising a acrylic polymer that lacks functional groups containing reactive hydrogen moieties.

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

11. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '938 combined with US '070 and further in view of US 6,139,866 ('866).

The combined teachings of EP '938 and US '070 are previously discussed as set forth in this office action.

Although EP '938 teaches analgesics, sedatives and hypnotic drugs to be delivered by the disclosed adhesive, however, the reference does not explicitly teach fentanyl as claimed by claims 15-17.

US '866 teaches suitability of fentanyl to be administered transdermally with little skin irritation and its ability to provide prolonged analgesic or anesthetic effect (abstract; col.1, lines 15-17).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pressure sensitive acrylic based adhesive obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and methacrylamide monomer to deliver analgesic, hypnotic or sedative as disclosed by EP '938 combined with US '070, and replace the analgesic, sedative or hypnotic drug with fentanyl taught by US '866. One would have been motivated to do so because US '866 teaches that fentanyl is suitable for transdermal administered with little skin irritation and prolonged analgesic or anesthetic effect. One would have reasonably

expected formulating polymer adhesive composition obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and methacrylamide and fentanyl wherein fentanyl is delivered to the skin without dermal irritation and provides prolonged analgesic or anesthetic effect.

Response to Arguments

12. Applicant's arguments filed 01/05/2009 have been fully considered but they are not persuasive. Applicants hereby repeat the argument regarding EP '938, and further argue that it would have been obvious to the skilled artisan to replace the analgesic, sedative or hypnotic drugs of EP '938 with fentanyl that is taught in US '866 as being suitable for transdermal administration.

In response to this argument, the examiner argument regarding EP '938 is hereby repeated. It is *prima facie* obvious to replace genus disclosed by the prior art by one of its species each of which is taught by the prior art that is useful for the same purpose. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

13. Claims 18, 19, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '938 combined with US '070 and further in view of US 5,458,885 ('885).

The combined teachings of EP '938 and US '070 are previously discussed as set forth in this office action.

Although EP '938 teaches two or more alkyl (meth)acrylate in the polymer, and US '070 teaches octyl acrylamide, however, the references do not explicitly teach 2-ethylhexyl acrylate and methyl acrylate as required by claims 18, 19, 21 and 23.

US '885 teaches transdermal system comprising polymer made of methyl acrylate and 2-ethylhexyl acrylate wherein the polymer is suitable to deliver basic active agents and their salts including analgesics (col.2, lines 43-55; col.3, lines 3-9, 64-67; col.4, lines 1-50; col.6, lines 37, 50-60; col.7, lines 1-9).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide pressure sensitive acrylic based adhesive obtained by polymerizing alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and octyl-acrylamide monomer as disclosed by EP '938 combined with US '070, and replace the acrylate monomer with methyl acrylate and 2-ethylhexyl acrylate as disclosed by US '885. One would have been motivated to do so because US '885 teaches that polymer made of methyl acrylate and 2-ethylhexyl acrylate is suitable to deliver basic active agents and their salts including analgesics. One would have reasonably expected formulating polymer adhesive composition made of alkyl acrylate monomer made of 2-ethylhexyl acrylate and methyl acrylate, and acrylamide monomer wherein the polymer provides successful delivery to basic therapeutic agents including analgesics.

The percentages of monomers in the polymer as claimed by claim 23 would have been adjusted by one having ordinary skill in the art according to the specific intended use and delivered drug.

Response to Arguments

14. Applicant's arguments filed 01/05/2009 have been fully considered but they are not persuasive. Applicants argue that the claimed invention would not have been obvious from the combined disclosures of EP '938 and US '885. There is no suggestion to use only those monomers that would result in an acrylate polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking and such an adhesive would be contrary to the teachings of EP '938,

In response to this argument, it is argued that the limitations of absence of functional groups and post-polymerization crosslinking are driven from the teachings of EP '938, and US '885 is relied upon for the solely teaching of methyl acrylate and 2-ethylhexyl acrylate as suitable monomer to deliver basic active agents and their salts including analgesics. This teaching would have motivated one having ordinary skill in the art to replace the acrylate monomer disclosed by EP '938 with methyl acrylate and 2-ethylhexyl acrylate disclosed by US '885 with reasonable expectation of having polymer adhesive composition made of alkyl acrylate monomer made of 2-ethylhexyl acrylate and methyl acrylate and acrylamide monomer wherein the polymer provides successful delivery to basic therapeutic agents including analgesics. It has been held

that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG